



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFA-305
Dockets
Public Health Service

Food and Drug Administration
Rockville MD 20857

December 9, 2004

Mr. C.A. McCampbell
Chief Operating Officer
O-AT-KA Milk Products Cooperative, Inc.
P.O. Box 718
Batavia, New York 14021-0718

Dear Mr. McCampbell:

This is to reply to your letter dated November 26, 2004, concerning the Food and Drug Administration's (FDA or the Agency) draft revised Compliance Policy Guide "Sec. 560.400 Imported Milk and Cream - Federal Import Milk Act (CPG 7119.05)."

In your letter, you provide comments on the draft revised CPG in response to the October 29, 2004, *Federal Register* Notice of Availability of the revised draft CPG at: <http://www.fda.gov/OHRMS/DOCKETS/98fr/04-24153.pdf>.

We have sent a facsimile of your letter to FDA's Division of Dockets Management (Dockets) for Docket No. 2004D-0453 to be included as comments received to the draft revised CPG. All information, including your name and address, contained in your letter will become part of the public record and may be posted to the Internet at: <http://www.fda.gov/ohrms/dockets/dailys/dailys04.htm>.

In the future you may send your comments directly to Dockets' electronic mail address at: FDAdocket@oc.fda.gov or to Dockets' land mail address at: Division of Dockets Management, FDA, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852; telephone (301) 827-6860; fax (301) 827-6870. The submission should include the docket number to ensure that your comments are correctly filed with the *Federal Register* Notice of Availability. FDA will consider all comments received on the draft revised CPG before issuing a final CPG.

We appreciate the time you have taken to provide us with your comments to the draft revised CPG.

Sincerely yours,

Lana L. Ogram
Director,
Division of Compliance Policy
Office of Enforcement

2004D-0453

C3/ANS



O-AT-KA Milk Products Cooperative, Inc.

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2 Pages Via Facsimile (240) 632-6861

November 26, 2004

Div. of Compliance Policy (HFC-230)
Office of Enforcement, Food & Drug Admin.
5600 Fishers Lane
Rockville, MD 20857

Re: Sec. 560.400 - Imported Milk and Cream - Federal Import Milk Act

To Whom It May Concern:

O-AT-KA is a progressive dairy cooperative dedicated to servicing customers around the globe with products and processing technology.

We receive and process approximately 750,000,000 pounds of quality US produced milk each year and import a large amount of globally produced milk proteins. Because of quality issues we have written lengthy detailed specifications, pretest all incoming lots before receiving the product, and still reject over 35% of the imported milk proteins. With all the concerns we have for food safety and the quality of our domestic supply, we were very disturbed after reviewing the Compliance Policy Guide (CPG) entitled "Sec. 560.400 - Imported Milk and Cream - Federal Import Milk Act".

This document has not been updated as milk quality has greatly improved and US milk producers are required to meet much more stringent standards. These requirements exceed those that are required under the Federal Import Milk Act (FIMA). FIMA does not require testing or set limits for somatic cell and coliform counts, animal drug residue testing or phosphatase testing. Also, microbiological test requirements and storage temperature limits are way too high in the FIMA.

The FIMA permit only addresses cows' milk and should be broadened to include sheep, goats and other lactating mammals that have their milk commercially collected and processed.

Many of the dairy products exempted fall into the milk and cream category, such as sour cream, cultured milk, acidified milk, dried milk, nonfat dry milk, and fortified nonfat dry milk.

Also, the CPG exempts commercially sterile dairy products. This was not provided for in the FIMA and should be removed from the CPG.

FIMA.1 Hr.doc
~~*FIMA.2.doc*~~

In an effort to continue supplying US consumers with the highest quality and safest food supply, we ask that you revise the CPG and update the FIMA. The FIMA should meet the stringent requirements under the Pasteurized Milk Ordinance and the definition of products should include those items in the CPG draft and additionally, sour cream, cultured milk, acidified milk, yogurt, cheese, ice cream, eggnog, dried milk, nonfat dry milk, nonfat dry milk fortified with vitamins A and D, other dehydrated milk products, and any product listed as requiring a permit that is processed and packaged in hermetically sealed containers.

If you have any questions regarding our comments or concerns please call me at our toll free number 1-800-828-8152.

Sincerely,

O-AT-KA Milk Products Coop., Inc.



C.A. McCampbell
Chief Operating Officer

CAM/dq

cc: Dan Meyer (ADPI)
Rob Byrne (NMPF)